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REMARKS

Applicant's undersigned representative is newly appointed to this case. Applicant's representative appreciates the Examiner extending the courtesy of a personal interview on January 12, 2006. The previously filed declarations were discussed and Applicant's representative agreed to provide a new declaration to overcome Bisson (FR 2785811).

Claims 1, 4, 7-11, 13, 15 and 17-29 are pending in this application, Claims 15 and 17-19 were withdrawn from consideration by the Examiner and are canceled in this amendment and response without prejudice to pursue them in a continuation or divisional patent application. Claims 1, 13, 20-23 and 28-29 are amended. New Claim 30 has been added. Claims 1, 4, 7-11, 13 and 20-29 stand rejected. By this amendment, Claims 1, 4, 7-11, 13, 20-30 are pending.

The present claims recite high density polyethylene particles. The concurrently filed declaration of the applicant, Dr. Wallace K. Dyer, and the declaration of Dr. Stephen W. Perkins address the conception of the invention, as claimed, at least as early as December, 1999 (declarations attached as Exhibits A and B, respectively). The previous declarations filed August 2, 2005, addressed use of expanded polytetrafluoroethylene (e-PTFE), which was not recited in the pending claims at that time. Applicant's representative asserts that this response and the new declarations are directly relevant to the pending claims that recite high density polyethylene particles, demonstrate conception before the May 19, 2000 publication date of Bisson (FR 2785811) and address issues raised in the new rejections under 35 U.S.C §112, second paragraph, 35 U.S.C §112, first paragraph, and 35 U.S.C. §103(a).

Claim Rejections under 35 U.S.C. § 102(a)

Claims 1, 4, 7, 13, 20-22, 28 and 29 are rejected under 35 U.S.C. §102(a) as being anticipated by Bisson (FR 2785811, published May 19, 2000, hereinafter Bisson).

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The declarations by Dr. Wallace K. Dyer and Dr. Stephen W. Perkins, filed August 2, 2005, mentioned the use of expanded polytetrafluoroethylene (e-PTFE), which was not recited in the pending claims at that time. The pending claims recite high density polyethylene particles. The new declarations by Dr. Wallace K. Dyer and Dr. Stephen W. Perkins filed with this response are directed to high density polyethylene particles.

Filed with this response is a declaration from the Applicant, Dr. Dyer, submitted under 37 C.F.R. §1.131 (attached as Exhibit A). This declaration states that the Applicant conceived of the invention by at least December of 1999. Further, the declaration states that the Applicant discussed his concept of the invention with Dr. Stephen W. Perkins in December of 1999. These discussions involved the materials suitable for use in compositions of the present invention, including high density polyethylene microparticles in a physiological carrier. Also described to Dr. Perkins were methods for injecting a composition comprising high density polyethylene microparticles in a physiological carrier, such as polyvinylpyrrolidone, into soft tissue for correction or repair of defects in the tissue. Dr. Perkins has executed a declaration stating these facts (attached Exhibit B).

The declaration of Dr. Dyer further states that he reduced this conception of the invention to practice thereafter through the filing of the present patent application. Dr. Dyer further declares that he diligently reduced the invention to practice through planning and directing work to make and characterize the composition, and through planning and execution of studies in animals to inject and test the composition.

Dr. Dyer's declaration asserts that biocompatible (micronized) polyethylene particles made from MEDPOR are recited in paragraphs 0030, 0043 and 0058 and in the Abstract of the pending patent application. The declaration further states that the polyethylene in MEDPOR is high density polyethylene.

Applicant's representative asserts that the new declarations, filed concurrently herewith, demonstrate conception of the invention, as recited in the pending claims that recite high density polyethylene particles, and demonstrate conception before the May 19, 2000 publication date of Bisson. Applicant has established possession of the currently claimed invention. Accordingly, Applicant respectfully asserts that the §102(a)

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rejection of Claims 1, 4, 7, 13, 20-22, 28 and 29 in view of Bisson has been overcome and requests its withdrawal.

Claim rejections under 35 U.S.C. §112, second paragraph

In the Office Action of November 2, 2005, a new rejection was asserted against Claims 1, 4, 7-11, 13 and 20-29 under 35 U.S.C. §112, second paragraph, as being vague and indefinite in view of the declarations filed August 2, 2005 that discussed e-PTFE which was not claimed at that time.

The new declarations filed concurrently herewith address high density polyethylene microparticles, as claimed. Accordingly, in view of the new declarations, Applicant respectfully asserts that the rejection of Claims 1, 4, 7-11, 13 and 20-29 under 35 U.S.C. §112, second paragraph, has been overcome and requests its withdrawal.

Claim rejections under 35 U.S.C. §112, first paragraph

In the Office Action of November 2, 2005, a new rejection was asserted against Claims 1, 4, 7-11, 13 and 20-29 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention at the time the application was filed. This is a new matter rejection.

Applicant's compositions, as claimed, comprise biocompatible micronized high density polyethylene particles having a size greater than 60 microns and a physiological carrier. The composition itself is biocompatible, moldable and has a consistency similar to the tissue it replaces. The biocompatible micronized high density polyethylene particles themselves are not soft. However, these micronized high density polyethylene particles are a component of the overall composition which can be easily molded after injection into soft tissue.

The specification discloses solid polymer particles as biocompatible (micronized) polyethylene particles made from MEDPOR in paragraphs 0030, 0043 and 0058 and in the Abstract. The polyethylene in MEDPOR is high density polyethylene, as declared by the Applicant (Exhibit A), and as known to one of ordinary skill in the art.

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Accordingly, in view of these remarks and identified support in the specification, Applicant respectfully asserts that the rejection of Claims 1, 4, 7-11, 13 and 20-29 under 35 U.S.C. §112, first paragraph, has been overcome and requests its withdrawal.

Claim rejections under 35 U.S.C. §103(a)

In the Office Action of November 2, 2005, a new rejection was asserted against Claims 1, 4, 7-11, 13 and 20-29 under 35 U.S.C. §103(a) as being unpatentable over Ersek et al. (U.S. Patent No. 5,336,263, hereinafter Ersek) and Catanese et al. (J. Biomed. Mater. Res. (Appl. Biomater. 1999, 48:187-192, hereinafter Catanese)).

The previous declarations filed August 2, 2005 addressed use of expanded polytetrafluoroethylene (e-PTFE), which was not claimed at that time. Applicant's representative asserts that the new Declarations, filed concurrently herewith, are directly relevant to the pending claims that recite high density polyethylene particles, not e-PTFE.

The declaration of Dr. Dyer asserts that biocompatible (micronized) polyethylene particles made from MEDPOR are recited in paragraphs 0030, 0043 and 0058 and in the Abstract of the pending patent application. The declaration further asserts that the polyethylene in MEDPOR is high density polyethylene.

The paragraph bridging columns 5 and 6 of Ersek were cited to indicate that polyethylene is a desirable material for soft tissue applications. Applicant respectfully disagrees and asserts that this paragraph states "For soft tissue, a soft elastomer such as silicone rubber is a desirable material for the textured particles...When a firm area is being treated, such as connective tissue or the like, polytetrafluoroethylene (Teflon) or polyethylene may be satisfactorily utilized" (Col. 5, lines 65-66, col.5, line 68-col. 6, line 3) emphasis added)). See also Column 11, lines 27-33 which states that "...other appropriate inert substances will mimic the durometer hardness of the host tissue being filled, with the softer materials, such as silicone rubber being utilized for normal subcutaneous fat tissue, and with ceramic materials being utilized for bone tissue.". In view of these passages, Applicant asserts that Ersek discloses that soft materials are to be used in soft tissues and hard materials are to be used in harder tissues such as cartilage and bone. In contrast, the biocompatible (micronized) polyethylene particles in

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Applicant's invention are hard, high density polyethylene particles for use in a composition administered to soft tissue.

As stated by the Examiner, Ersek is silent with regard to the use of high density polyethylene particles, as recited in Applicant's pending claims. Catanese discloses e-PTFE and is also silent with regard to high density polyethylene particles.

Accordingly, in view of the new declarations that address high density polyethylene particles and assert that the polyethylene in MEDPOR is high density polyethylene, the location of support in the specification for biocompatible (micronized) polyethylene particles made from MEDPOR, and the silence of Ersek and Catanese with regard to high density polyethylene particles, Applicant respectfully asserts that Ersek and Catanese, alone or in combination do not teach, suggest or provide motivation to derive Applicant's invention, as claimed. For at least these reasons, Applicant believes the rejection of Claims 1, 4, 7-11, 13 and 20-29 under 35 U.S.C. §103(a) has been overcome and requests its withdrawal.

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CONCLUSION

Based upon the amendments and remarks provided above, Applicant believes the pending Claims are in condition for allowance. A Notice of Allowance is therefore respectfully solicited.

This response is considered timely filed and fully responsive to the Office Action of November 2, 2005. No additional fees are believed due; however, the Commissioner is hereby authorized to charge any additional fees that may be required, or credit any overpayment, to Deposit Account No. 11-0855.

If the Examiner believes any informalities remain in the application that may be corrected by Examiner's Amendment, or there are any other issues that can be resolved by telephone interview, a telephone call to the undersigned attorney at (404) 745-2470 is respectfully solicited.

Respectfully submitted,



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